Message Text

PAGE 01 STATE 166320

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C O R R E C T E D C O P Y - LINE 7 PARA 9 OMITTED

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SUBJECT: REGULATION OF IMPORT AND SALES OF MEDICAL EQUIPMENT IN U. S.

REF: TOKYO 8708

1. SPHYGMOMANOMETERS ARE MEDICAL DEVICES DEFINED IN THE FEDERAL FOOD, DRUG, AND COSMETIC ACT AND AS SUCH ARE SUBJECT TO THIS ACT AND REGULATIONS PROMULGATED THEREUNDER. ALL MEDICAL DEVICES, BE THEY OF DOMESTIC OR FOREIGN MANUFACTURE, MUST COMPLY WITH THIS ACT AND REGULATIONS.

2. THE AUTHORITY TO REGULATE SUCH DEVICES HAS BEEN ESTABLISHED BY ENACTMENT OF THE ORIGINAL FOOD, DRUG, AND COSMETIC ACT OF 1938 AND SUBSEQUENT REVISIONS, IN-CLUDING THE MOST RECENT MEDICAL DEVICE AMENDMENTS OF 1976 SIGNED INTO LAW ON MAY 28 OF THIS YEAR.

UNCLASSIFIED

PAGE 02 STATE 166320

3. IN ACCORDANCE WITH THE NEW MEDICAL DEVICE AMENDMENTS, SPHYGMOMANOMETERS HAVE BEEN TENTATIVELY CLASSIFIED INTO THE CATEGORY OF PERFORMANCE STANDARDS, CLASS II DEVICES. TO DATE SUCH STANDARDS FOR THESE DEVICES HAVE NOT BEEN

ESTABLISHED UNDER THESE NEW AMENDMENTS.

4. WHEN PROCEEDINGS ARE INITIATED FOR THE ESTABLISHMENT OF A PERFORMANCE STANDARD FOR SECRETARY OF HEW SHALL PUBLISH IN THE FEDERAL REGISTER A NOTICE INVITING ANY PERSON, INCLUDING ANY FEDERAL AGENCY, TO SUBMIT TO THE SECRETARY, WITHIN SIXTY DAYS AFTER THE DATE OF PUBLICATION OF A NOTICE, AN EXISTING STANDARD AS A PROPOSED STANDARD FOR SUCH A DEVICE, OR OFFER, WITHIN SIXTY DAYS AFTER THE DATE OF PUBLICATION OF THE NOTICE, TO DEVELOP SUCH A PROPOSED STANDARD.

5. IF A STANDARD IS ACCEPTABLE, THE SECRETARY SHALL PUBLISH IN THE FEDERAL REGISTER A PROPOSED PERFORMANCE STANDARD FOR THE DEVICE AT WHICH TIME INTERESTED PARTIES ARE OFFERED AN OPPORTUNITY TO COMMENT ON THE PERFORMANCE STANDARD. AFTER CONSIDERATION OF SUCH COMMENTS THE SECRETARY SHALL PROMULGATE A REGULATION ESTABLISHING A PERFORMANCE STANDARD AND PUBLISH SUCH STANDARD IN THE FEDERAL REGISTER. THIS REGULATION ESTABLISHING A PERFORMANCE STANDARD SHALL SET FORTH THE DATE OR DATES UPON WHICH THE STANDARD SHALL TAKE EFFECT, BUT NO SUCH REGULATIONS MAY TAKE EFFECT BEFORE ONE YEAR AFTER THE DATE OF ITS PUBLICATION, UNLESS THE SECRETARY DETERMINES THAT AN EARLIER EFFECTIVE DATE IS NECESSARY FOR THE PROTECTION OF THE PUBLIC HEALTH AND SAFETY. PERFORM-ANCE STANDARDS MAY IN ACCORD WITH THE ACT, BE REVOKED OR AMENDED BY THE SECRETARY WHEN DEEMED NECESSARY FOR THE PUBLIC HEALTH AND SAFETY.

6. UNTIL THE ESTABLISHMENT OF SUCH PERFORMANCE STANDARDS FOR SPHYGMOMANOMETERS THE FOOD AND DRUG ADMINISTRATION WILL CONTINUE TO REQUIRE THAT THESE DEVICES ARE SAFE AND EFFECTIVE FOR THEIR INTENDED USE AND ADEQUATELY LABELED. ALL SPHYGMOMANOMETERS, OF FOREIGN AND WELL AS DOMESTIC ORIGIN MUST COMPLY WITH THE TESTS FOR ACCURACY AND LEAKAGE DEFINED IN THE FEDERAL SPECIFICATION,
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SPHYGMOMANOMETERS, ANEROID AND MERCURIAL GG-S-618C, OCTOBER 31, 1960, AND BE ADEQUATELY LABELED. SAMPLING PROCEDURES FOR ACCURACY TESTING MUST BE FOLLOWED IN ACCORD WITH MILITARY STANDARD, SAMPLING PROCEDURES AND TABLES FOR INSPECTION BY ATTRIBUTES MCL-STD-105D 29 APRIL 1963. COPIES OF THESE TWO PUBLICATIONS MAY BE OBTAINED FROM THE SUPERINTENDENT OF DOCUMENTS, U.S. GOVERNMENT PRINTING OFFICE, WASHINGTON, D.C., 20402.

7. THERE ARE NO SUCH SIMILAR FEDERAL SPECIFICATIONS FOR ELECTRONIC SPHYGMOMANOMETERS, HOWEVER SUCH INSTRUMENTS ARE ALSO DEVICES AS DEFINED BY THE ACT. SUCH INSTRUMENTS ARE SUBJECT TO THE SAME ACCURACY, LEAKAGE AND LABELING

REQUIREMENTS AS ABOVE DESCRIBED AND ARE SUBJECT TO SAMPLING AND TESTING WHEN DEEMED NECESSARY.

8. THERE IS NO PROVISION IN THE ACT FOR THE CERTIFICATION OF DEVICES BY THE FOOD AND DRUG ADMINISTRATION. THE RESPONSIBILITY FOR SAFETY AND EFFICACY AND LABELING OF DEVICES REMAINS THE RESPONSIBILITY OF THE MANUFACTURERS OR SUBSEQUENT INTERMEDIARIES WHO ASSUME THIS RESPONSIBILITY. HENCE, ANY DEVICES IMPORTED INTO THE UNITED STATES ARE SUBJECT SAMPLING AND TESTING TO DETERMINE THEIR SAFETY AND EFFICACY AND ADEQUACY OF LABELING AS DEEMED NECESSARY.

9. SOME INDIVIDUAL STATES HAVE MEDICAL DEVICE LEGISLATION. COMPLIANCE WITH THE LAWS AND REGULATIONS OF THESE STATES ALSO REMAIN THE RESPONSIBILITY OF THE MANUFACTURER OR SUBSEQUENT INTERMEDIARIES WHO ASSUME THAT RESPONSIBILITY. EXPERIENCE IN THE PAST HAS SHOWN, HOWEVER THAT COMPLIANCE WITH THE FEDERAL FOOD, DRUG, AND COSMETIC ACT IS GENERALLY IN AGREEMENT WITH INDIVIDUAL STATE LAWS.

10. PRIVATE AGENCIES, SUCH AS THE AMERICAN MEDICAL ASSOCIATION, BETTER BUSINESS BUREAU AND OTHERS MAY OPT TO IMPOSE SPECIFIC NEEDS AND REQUIREMENTS FOR PURCHASES MADE BY THEM, HOWEVER THESE AGENCIES MUST ALSO COMPLY WITH THE ACT AND REGULATIONS.

11. MANUFACTURERS INTERESTED IN OBTAINING REVIEW AND
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COMMENT ON THE ADEQUACY OF LABELING FOR THESE DEVICES MAY SUBMIT THEIR LABELS AND LABELING TO THE BUREAU OF MEDICAL DEVICES AND DIAGNOSTIC PRODUCTS, 8757 GEORGIA AVE., SILVER SPRING, MARYLAND, 20910. A ROUGH DRAFT OF THE PROPOSED LABELING WILL SUFFICE. LABELING SHOULD BE IN THE ENGLISH LANGUAGE. KISSINGER

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